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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,470	12/06/2002	Naoki Tohdoh	0020-4850P	7636

2292 7590 06/21/2005

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EXAMINER	
SEETHARAM, SARASWATHY	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,470	TOHDOH ET AL.	
	Examiner	Art Unit	
	Saraswathy Seetharam, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.O.O.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The inventions listed in Groups I-Vii do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: PCT Rule 13.2 and C.F.R.1.475 define "special technical feature" as those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art: 37 C.F.R.(d) states that, if multiple products, processes of manufacture, or uses are claimed, the claims will be considered as the main invention, along with each of the other categories related thereto. The main invention is a DNA encoding a protein comprising an amino acid sequence containing deletion, substitution and or addition of amino acid residues SEQ ID No.2 or 4 having an inhibitory effect on cancer cell proliferations.
Srivastava et al. (Urology, 1995, Vol; 46, pp843-848) disclose a recombinant adenoviral vector expressing high levels of wild type p53 with an inhibitory effect on cell proliferation in human prostate cancer cells. As set forth above in view of the teachings from Srivastava et al. the groups are not so linked as to form a single general concept under PCT Rule 13.2 because no special technical feature exists for Group I. Note that PCT Rule 13 does not provide for multiple products or methods within a single application.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5,7-11,18-26,31 and 16 in part- drawn to a DNA encoding a protein comprising amino acid sequence containing deletion, substitution, and or addition of one or more amino acid residues in the amino acid sequence of SEQ ID No. 2 or 4, said protein having an inhibitory effect on cancer cell proliferation, said DNA cloned from chromosomal library, an expression vector, an adenovirus vector, a pharmaceutical composition inhibiting proliferation, composition facilitating neurotrophic factor secretion, and treating neuro degenerative diseases.

Group II, claim 12 and claim 15 in part drawn to a method for detecting the expression of DNA comprising the base sequence of SEQ ID No. 1 or 3 and diagnosing cancer.

Group III, claim(s) 6,16 in part and 27-29 drawn to a protein, a pharmaceutical composition comprising the protein, a composition facilitating secretion of neurotrophic factor comprising an active ingredient as a protein of SEQ ID No.2 or 4, a protein encoded by a DNA (SEQ ID No. 1 or 3) and a microorganism that contains the said DNA.

Group IV, claim(s) 13 drawn to an antibody that binds to the said protein.

Group V, claim(s) 14,15 in part, drawn to a method of detecting the protein and diagnosing cancers.

Group VI, claim(s) 17 and 30, drawn to a (known) composition inhibiting proliferation of cancer cells comprising enhancing the expression of a DNA (SEQ ID No. 1 or 3) and a composition facilitating neurotrophic factor secretions.

Group VII, claim(s) 32, drawn to a method for facilitating secretion of neurotrophic factors which comprises the enhancing the expression level of a DNA (SEQ ID No. 1 or 3) or the production level of a protein (SEQ ID No. 2 or 4).

The inventions listed as Groups I- VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above in view of the teachings from Srivastava et al. the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature shared by Groups I- IV is not special.

Three different products are presented in Groups I, III and IV which do not share a common core structure, nor a common activity or property. For instance the DNA of claim 1 is not required to encode the protein of claims 6 or 16. Furthermore, the information provided in Group I could be used to make a materially different protein than that of Group III. In addition,

while a protein of Group III can be made by using some but not all of the polynucleotides that fall within the scope of Group I, it can also be isolated using affinity chromatography. The antibody of Group IV includes IgG molecules comprising heavy and light chains containing constant and variable regions,, framework regions and CDRs. Groups II, V and VII are methods of using the products of Groups I, III, and IV. Group II requires the isolation of RNA from normal and cancer cells and Northern hybridization for detection of expression, which is not required for the claimed method in Group VII. Conversely, Group VII requires vector construction, infection, cell culture, and analysis of secreted product, which are not required in the claimed method in Group II. Thus the inventions I-VII are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different searches in the patent literature, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Saraswathy Seetharam, PhD whose telephone number is 571-272-3113. The examiner can normally be reached between M-F, 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saraswathy Seetharam, PhD
Examiner
Art Unit 1642

LARRY R. HELMS, PH.D
PRIMARY EXAMINER